



# ARISE & SHINE

February 25, 2005

Office of Nutritional Products, Labeling and  
Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

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## SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, **Arise & Shine Herbal Products, Inc.** notifies FDA that it has begun using the following statement:

For the following herbal extracts: (1)Eyebright, (2)Ginkgo Leaf, (3)Bilberry, (4)Nettle, (5)Echinacea, (6)Grape Seed, (7)Ginseng, (8)Valerian Root (9)Chamomile, (10)Hops and (11)Skullcap

which contain the statutory statement, on the following product(s):

(1)Eyebright may ease oversensitivity to light, (2)Ginkgo may increase blood circulation to the eyes, (3)Bilberry contains bioflavonoids that support better night vision and eye health, (4)Nettle may strengthen the immune system and enhance resistance to allergens/allergies, (5) Echinacea may strengthen the immune system and enhance resistance to allergens/allergies, (6)Grape Seed may strengthen the immune system and enhance resistance to allergens/allergies, (7)Ginseng may strengthen the immune system and enhance resistance to allergens/allergies, (8)Valerian Root contains calming properties that may aid in more restful, refreshing sleep, (9)Chamomile contains calming properties that may aid in more restful, refreshing sleep, (10)Hops contain calming properties that may aid in more restful, refreshing sleep, (11)Skullcap contain calming properties that may aid in more restful, refreshing sleep.

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I certify that the foregoing is complete and accurate, and that **Arise & Shine Herbal Products, Inc.** has substantiation that the statements are truthful and not misleading.

Very truly yours,

**Arise & Shine Herbal Products, Inc.**

By Sarah Adkins